

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 19, 2007 has been entered.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Charles Mersereau on March 3, 2008.

IN THE CLAIMS

3. Claims 1-131 have been canceled.
4. Claims 132-135 have been added:

132. A method of identifying a compound that selectively inhibits cytokine-stimulated T cell (T_{ek} cell) induced production of $TNF\alpha$ by monocytes at least two-fold greater than the compound inhibits T cell antigen receptor-stimulated T cell (T_{ter} cell) induced production of $TNF\alpha$ by monocytes

wherein said method comprises the following steps:

- (a) providing a population of T_{ek} cells wherein said T_{ek} cells have been produced by incubating normal human peripheral blood T cells with cytokines selected from the group consisting of:
 - (i) IL-15;

- (ii) IL-6, TNF α and IL-2; and
- (iii) IL-6, TNF α and IL-15;
- (b) providing a population of T_{h1} cells wherein said T_{h1} cells have been produced by incubating normal human peripheral blood T cells with one or more anti-T cell antigen receptor antibodies which activate T cell antigen receptors;
- (c) incubating separate cultures of T_{h1} cells and T_{h2} cells with a compound to be tested;
- (d) resuspending the cultures of T_{h1} cells and T_{h2} cells in the absence of the test compound;
- (e) fixing the cultures of T_{h1} cells and T_{h2} cells;
- (f) co-culturing equal portions of each of said fixed T_{h1} cells and T_{h2} cells with monocytes to allow stimulation of the monocytes; and
- (g) assaying for TNF α production by said monocytes,

wherein the method identifies a compound that selectively inhibits T_{h1} cell induced production of TNF α by monocytes at least two-fold greater than the compound inhibits T_{h2} cell induced production of TNF α by monocytes.

133. A method according to claim 132 wherein the compound identified is an antibody having specificity for T_{h1} cells.

134. A method according to claim 132 wherein said compound has efficacy in the treatment of rheumatoid arthritis.

135. A method according to claim 132 wherein said anti-T cell antigen receptor antibody is an anti-CD3 antibody.

REASONS FOR ALLOWANCE

5. The following is an examiner's statement of reasons for allowance: upon reconsideration of the prior obviousness rejection under 35 U.S.C. § 103(a) over Sebbag in view of Parry, in particular the non-obviousness of practicing a method of identifying a compound that selectively inhibits T_{ek} cell induced production of $TNF\alpha$ by monocytes at least two-fold greater than the compound inhibits T_{er} cell induced production of $TNF\alpha$ by monocytes, and the applicant authorized examiner's amendment made herewith (see attached interview summary and e-mail messages of March 3, 2008) the instant claims are in condition for allowance.

Claims 132-135 are allowed.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARY SKELDING whose telephone number is (571)272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
March 3, 2008

/Michail A Belyavskyi/
Primary Examiner, Art Unit 1644